



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/806,028

03/22/2004

Robert Karlsson

B 521

1001

22840

7590

05/02/2008

GE HEALTHCARE BIO-SCIENCES CORP.
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

05/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/806,028 | Applicant(s) KARLSSON ET AL. | |
| | Examiner JAMES L. GRUN | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13, 15-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 15-29, 31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/01/08</u> . | 6) <input type="checkbox"/> Other: _____ |

The amendment filed 01 February 2008 is acknowledged and has been entered. Claims 11, 12, 14, and 32 have been cancelled. Claims 1-10, 13, 15-31, and 33-44 remain in the case. Claims 30 and 36-44 have been withdrawn from further consideration as being drawn to a non-elected species or invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-10, 13, 15-29, 31, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, in the absence of further written description and guidance from applicant, one would not be assured of the ability to practice the invention as instantly claimed because applicant merely assumes a critical micellar concentration (CMC) for the detergent, not the mixture, in the examples and provides no evidence that a vesicular structure was formed at all

Art Unit: 1641

concentrations of detergent and oligonucleotides mixtures used in the conditions of the experiment, particularly since the CMC for the detergent alone or, as known to the art, in the presence of DNA is higher than many, or at least several, of the concentrations used by applicant and asserted as containing micelles. Moreover, Chatterjee et al. (Biophys. Chem. 98: 313, 2002) also teach that high concentrations of cetyltrimethylammonium bromide (CTAB) relative to DNA, as used in the instant exemplifications, results in precipitation of DNA (see e.g. page 325). Thus, it is further unknown and unpredictable that the invention functions in the manner as claimed because an oligonucleotide target molecule complexed to a vesicular structure is unpredictable and not in evidence.

Applicant's arguments filed 01 February 2008 have been fully considered but they are not deemed to be persuasive.

Applicant urges that it is not proper to assume that the CMC conditions for large and small molecules would be comparable and therefore that the examiner cannot assume that the CMC would be as high as that taught in Chatterjee et al. This is not found persuasive for a number of reasons. Firstly, as set forth, applicant has provided no evidence of a predictable vesicular structure and has merely provided unsupported assumptions regarding the CMC of CTAB which are less than about 1/3 of even the critical aggregation concentration or the CMC published for CTAB in the presence or absence of other molecules. The argument is unpersuasive also because the examiner did not rely only on the teachings of Chatterjee et al. regarding the CMC of CTAB with DNA, but also upon the observation that applicant's concentrations were below the CMC of CTAB alone. Moreover, applicant's assertions that there is no doubt that vesicular structures were formed at the higher concentrations of the cationic

Art Unit: 1641

detergents exemplified were not found persuasive because a complex of target with vesicular structure is not in evidence because of the complication of precipitation.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15, 18-21, and 25-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Karlsson et al. (Anal. Biochem. 300: 132, 2002) for reasons similar to those of record. In addition to the teachings of the reference set forth previously, the examiner would note that the mixed micelles of the method of the reference comprised octylglucoside and lipids, considered herein a low molecular weight organic molecule, delivered the lipids to the surface of the sensor, and immobilized the lipids to the surface, and to the immobilized rhodopsin protein, when the octylglucoside was washed from the micelles.

Applicant's arguments filed 01 February 2008 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Art Unit: 1641

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-10, 13, 15, 26, 31, and 33-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nikiforov et al. (US 5,610,287) for reasons similar to those of record. The examiner would note that the presence of vesicular structures in the mixture of the cationic detergent 1-ethyl-3-(3'-dimethylaminopropyl)-1,3-carbodiimide hydrochloride (EDC) (see cols. 7-8) with oligonucleotides used in the immobilization of the oligonucleotides onto negatively-charged solid surfaces by both covalent or non-covalent binding (see e.g. cols. 14-16, Table 3) cannot be determined by the examiner.

Applicant's arguments filed 01 February 2008 have been fully considered but they are not deemed to be persuasive. Applicant's arguments regarding CTAB were not found persuasive for the reasons set forth above regarding the use of EDC.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Art Unit: 1641

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chatterjee et al. (Biophys. Chem. 98: 313, 2002) teach micelles of cetyltrimethylammonium bromide (CTAB) and deoxyribonucleic acid.

Reddy et al. (US 5,648,213) teach conventional alternatives for binding oligonucleotides to solid supports (see e.g. col. 10).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
May 2, 2008

/Christopher L. Chin/

Primary Examiner, Art Unit 1641